

AMENDMENTS TO THE SPECIFICATION:

Page 21, last paragraph, continuing onto page 22:

The preferred embodiment of the fastener 10, shown in Figs. 1A-1C, is essentially that of the body of an extension spring having coils 12. At rest, the coils of this fastener 10 are spring biased towards each other so that a force ~~is~~ FA is required to effect separation of ~~said~~ the coils. The force at which the coils just begin to separate is the preload value for the fastener. Additional force causes separation of the coils 12 as a function of the gradient of the fastener. Shown in Fig. 1C, layers of tissue 18 that are trapped between adjacent coils 12 of the fastener will be clamped with a force F1 being substantially normal to the surface of the tissue 18 and having a value somewhat higher than the preload value of the fastener. This force, which is a function of fastener material, dimensions and winding technique, is chosen to insure hemostasis when vascular tissue is to be clamped. It should be noted that a compression spring could be used in place of an extension spring so long as the tissue is thick enough that it is compressed between the coils of the fastener once it is in place.

The theory and practice of winding preloaded coils of metallic wire is routinely practiced in the manufacture of extension springs and is well known to those skilled in the art.

Page 24, second paragraph:

The fastener 40 in Fig. 4 has symmetrical coils 42 to distribute stress uniformly on both sides of the tissues to be joined.

Page 25, last paragraph, continuing onto page 26:

For all fasteners described above, the leading end 21 of the fastener, shown in Fig. 2, can be sharpened for ease of penetration either by cutting the wire on a bias or by tapering the end to a sharp point during manufacture of the fastener. The bias cut is commonly used to make sharp points on conventional staples and taper pointing is used to make a certain class of suture needles. Both techniques are well known to those skilled in the art. Other sharpening techniques such as trocar points may also be effectively applied to the fastener. Alternatively or additionally, a tube 154 of a ~~delivery~~ deployment instrument 150 that houses the fastener, as shown in Figs. ~~5A-5F and 6A-6F~~ 9A-9D,

can have a sharpened tip which is used to penetrate the tissue 18 prior to pushing the fastener from said tube.

Page 26, last paragraph, continuing onto page 27:

Figs. 5A-5F show a first embodiment of a deployment instrument 50 and the method for inserting the fastener. The deployment instrument 50 consists of a plunger 52 having a head portion 60, a needle 54 having a head portion 55, and a sleeve 51 having a head portion 57 and a stop 56. The plunger 52 fits slidably inside a lumen of the needle 54, which fits slidably inside of the sleeve 51. Figs. 5A-5F show the fastener 10 being used to attach a graft 16 to a blood vessel having a first layer of tissue 14 and an opposite wall 17 (FIG. 5B). The fasteners described herein, however, can be used for any layers of material or tissue. Furthermore, the ~~delivery~~ deployment instrument 50 can deliver any of the fasteners described herein.

Page 27, last paragraph, continuing onto page 28:

For the deployment instrument shown in Figs. 5A-5D, the head portion 60 of the plunger 52 has two stops 62, 64 attached to it. One of the stops 62

pivotally engages ~~of~~ the head portion 55 of the needle 54 and also pivotally engages a stop 56 of the head portion 57 of the sleeve 51. The other stop 64 can engage the head portion 55 of the needle 54. These stops 62, 64 are used to control the amount of depth that the needle and/or fastener may be inserted into the tissue 18.

Page 30, the full paragraph:

Figs. 6A through 6F show a second embodiment of ~~the delivery~~ deployment instrument 100 which can deliver any of the fasteners described herein. ~~The~~ A plunger 102 has a head portion 110 having both a short stop 114 and a long stop 112 attached to it. ~~The~~ A head portion 105 of ~~the~~ a needle 104 has two slots 116 and 118 to accept the long ~~112~~ and short ~~114~~ stops 112, 114, respectively, at different times of the process. The needle 104 is slidably accepted by a sleeve 101 having a head portion 107. The tip of the ~~delivery~~ deployment instrument 100, fastener 10 and needle 104 for Figs. 6A-6F appear the same as in Figs. 5A-5F, respectively, and are not shown for the sake of clarity.

Page 32, last paragraph:

It should be apparent that many types of stops could be used to position the needle 54, 104 and plunger 52, 102 of the deployment instruments 50, and 100, ~~105~~. For example, the needle could function with only a single stop attached to the shaft of the plunger. Alternatively, visual indicators could be used, but would be inherently less reliable. It should be apparent that the ~~delivery~~ deployment instruments ~~as~~ shown in Figs. 5A-5F and 6A-6F could function properly without the short stops 64, 114, but not as reliably. Also, the delivery instruments, ~~as~~ shown in Figs. 5A-5F and 6A-6F, could function without the sleeve 51 or 101, respectively. It should be apparent that a plurality of any of these deployment instruments described herein could be integrated in a single deployment instrument for sequential or simultaneous deployment of the fastener.

Page 33, second paragraph:

Fig. 8 shows an enlarged view of the needle of either Figs. 5A-5F or 6A-6F with a fastener inside of it. A typical aspect ratio of the length to diameter for this device can be in the order of 40 or 50 for

less invasive use. The diameter of the fastener is preferably between 0.012 to 0.014 of an inch, more preferably its diameter is 0.013 of an inch, the inside diameter of ~~the~~ a lumen 53 of the needle 54 is preferably 0.017 of an inch and the outside diameter of the needle is preferably 0.025 of an inch.

Page 37, second full paragraph:

The present invention also provides a system for improving fixation of endovascular grafts used to treat aortic aneurysms or occlusive disease of the aorta. In addition, the present invention may be used to treat acute and chronic dissections of the aorta including those of the arch, thoracic and abdominal aorta.

Page 39, first paragraph:

Fixation of the graft to the neck of the aneurysm is critical. Failure to achieve fixation prevents complete exclusion of the blood flow from the aneurysm sac. Thus the sac remains pressurized with normal systematic blood pressure, which will result in enlargement and eventual rupture of the aneurysm. Because fixation of the graft is frequently dependent on friction, the length of normal aorta below the renal

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arteries (the neck) is the limiting factor in the successful deployment of these new graft devices. In general, the neck needs to be approximately 14-20 mm in length for successful deployment. Other factors limiting adequate apposition using stent technology include the size of the neck, whether it has a regular circumference or whether it bulges, and the angle between the neck and the aneurysm.

Page 43, last paragraph, continuing onto page 44:

Looking now at Figs. 10-21, another preferred embodiment of the invention is shown including an endovascular grafting and repair system 200 and a method for delivery of fasteners using the system 200. In this preferred embodiment of the present invention, an endovascular grafting and repair instrument 200 includes a guide wire 205, a balloon catheter 210, delivery tubes 215 (Fig. 12), a delivery tube deployment means 220 (shown as an inner sheath 220), an endovascular graft delivery sheath 235, a plunger 245, and fasteners 250 (Fig. 14). ~~System 200~~ The system may be used to secure graft devices to the interior of a vascular structure, such as graft devices that rely on friction or hook technology to fix the proximal end of

an endovascular graft to the interior of a vascular structure.

Page 44, the full paragraph:

Still looking at Figs. 10-21, guide wire 205 is shown supporting balloon catheter 210 to allow placement of endovascular grafting and repair ~~system~~ instrument 200 in a vessel 255 (Fig. 11). Generally, guide wire 205 is a stiff wire. In the preferred embodiment of the invention, vessel 255 is shown and discussed in the context of an aorta 255, but is not limited to such a vessel. Balloon catheter 210 may provide intra-operative angiography to monitor deployment of fasteners 250 and balloon infiltration to ensure full expansion of endovascular graft 225 after attachment to the wall of aorta 255. Such balloon infiltration also provides excellent apposition of graft 225 to aorta 255.

Page 47, last paragraph:

Referring now to Figs. 10-15, plunger 245 is shown having a proximal end 265 and a distal end (not shown, located adjacent to a fastener 250 located at the distal end 260 of a delivery tube 215). Plunger 245 is



configured for delivery of fasteners 250 once delivery tubes 215 have penetrated aorta 255. The portion of fastener 215 placed on the distal side of aorta 255 is delivered by moving the distal portion ~~265~~ of plunger 245 a predetermined distance toward ends 260 of delivery tubes 215. The portion of fastener 250 placed on the proximal side of aorta 255 is subsequently deployed by withdrawing delivery tubes 215 away from aorta 255 and away from fastener 250 in the wall of aorta 255. In addition, the withdrawal of delivery tubes 215 away from the wall of aorta 255 further decreases the length of delivery tube 215 surrounding fastener 250 while plunger 245 remains at a fixed location relative to the wall of aorta 255.

Page 48, a paragraph continuing onto page 49:

~~Endovascular~~ The endovascular grafting and repair system 200 is preferably used in the following manner to deliver a graft (i.e., endovascular graft 225 and stent 230) to the interior of a vascular structure (e.g., aorta 255). First, guide wire 205 is positioned in the aorta. Then the remainder of the system, encased in outer sheath 235, is moved down guide wire 205 until graft 225 is properly positioned in the

aorta. Then outer sheath 235 is withdrawn, allowing graft 225 and stent 230 to deploy against the interior of aorta 255. Then inner sheath 220 is withdrawn, allowing delivery tubes 215 to angulate outward. Next, inner sheath 220 and delivery tubes 215 are advanced distally, causing the sharp distal ends 260 of delivery tubes 215 to penetrate through graft ~~255~~ 225, stent 230 and the walls of aorta 255. As this occurs, delivery tubes 215 carry fasteners 250 outward so that portions of fasteners 250 also extend through graft 225, stent 230 and aorta 255. Then plunger 245 is advanced so as to deploy the outer ends of fasteners 250 against the outside wall of aorta 255. Next, delivery tubes 215 are retracted, thereby causing the inner ends of fasteners 250 to be deployed against the inside of graft 225. As a result, graft 225 and stent 230 will be secured to aorta 255 by the coils 12 of fasteners 250. Then balloon catheter 210 is inflated so as to ensure full expansion of graft 225 and stent 230, whereby to ensure close apposition of the graft to the aortic wall.

Page 49, last paragraph:

It should also be appreciated that the system 200 described herein above can be used to secure a previously-deployed endovascular graft to the wall of an aorta. More specifically, in some situations a previously-deployed endovascular graft may be in danger of migrating within the aorta. In this case, the system 200 (without graft 225, stent 230 and inner sheath 220) may be used to set fasteners 250 through the previously-deployed graft, whereby to ensure proper fixation of the graft relative to the aorta.